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Application No.	:	**2,506,526**
Owner	:	YU, MANG; FANG, FANG
Title	:	**BROAD SPECTRUM ANTI-VIRAL THERAPEUTICS AND PROPHYLAXIS**
Classification	:	A61K 38/16 (2006.01)
Your File No.	:	**PAT 59432W-1**
Examiner	:	G. A. Candeliere

YOU ARE HEREBY NOTIFIED OF A REQUISITION BY THE EXAMINER IN ACCORDANCE WITH SUBSECTION 30(2) OF THE *PATENT RULES*. IN ORDER TO AVOID ABANDONMENT UNDER PARAGRAPH 73(1)(A) OF THE *PATENT ACT*, A WRITTEN REPLY MUST BE RECEIVED WITHIN 6 MONTHS AFTER THE ABOVE DATE.

This application has been examined taking into account applicant's correspondence received in this office on September 27, 2007.

The number of claims in this application is 58.

A search of the prior art has revealed the following:

Reference Applied:

Publication			
Proc Natl Acad Sci U S A	April 17, 2003 (Epub)	100(9):5016-5021	Root MJ et al

Root et al disclose a 5-Helix polypeptide fused to a Pseudomonas exotoxin protein. This fusion protein recognizes and kills HIV-1-infected cells expressing Env. Further, the 5-Helix fusion protein also targets the prehairpin intermediate and interferes with the Trimer-of-Hairpins/Fusion process (see page 5017, first paragraph; figure 1 and reference 16).

The examiner has identified the following defects in the application:

Claim 1 does not comply with paragraph 28.2(1)(*b*) of the *Patent Act*. Root et al disclosed the claimed subject matter before the claim date. The claimed priority date of November 22, 2002 based on the US provisional application 60/428535, for the subject matter of claim 1, was found not to be valid. There is no substantial support in the priority document for defining a therapeutic domain of undetermined structure by the chemical property of possessing any enzyme activity which prevents infection by a pathogen. There is also no substantial support in the priority document for combining such a therapeutic activity with any anchoring activity of undetermined structure. Thus, Root et al disclosed a polypeptide comprising a therapeutic domain and an anchoring domain prior to the filing date of the instant application. The gp41 binding site (anchoring domain) found on both the 5-Helix polypeptide and on the 5-Helix/Pseudomonas exotoxin polypeptide anchors the fusion proteins. The anchoring domain binds to a molecule at or near the surface of a eukaryotic cell. The C38 portion, a therapeutic domain, of the 5-Helix fusion protein and the Pseudomonas exotoxin portion, also a therapeutic domain, of the 5-Helix/Pseudomonas exotoxin polypeptide acts by interfering with the fusion, cell survival and spreading of infection. Thus, the therapeutic domain has at least one extracellular enzyme activity or enzyme inhibitor activity for preventing infection of a eukaryotic cell by a pathogen. Therefore, the prior art encompasses the claimed subject matter.

Claim 1 does not comply with section 84 of the Patent Rules for being directed to the desired result rather than to the combination necessary to achieve that result as described in the description. Applicant states that the domains are now defined not by a desired result, but by their respective activity required for each domain to achieve the claimed result. Applicant further states that claim 1 now clearly defines the chemical properties of the therapeutic domain and anchoring domain respectively. However, there is no substantial support in the description for defining a therapeutic domain of undetermined structure by the chemical property of possessing any enzyme activity which prevents infection by a pathogen. There is also no substantial support for combining such a therapeutic activity with any anchoring activity of undetermined structure. Applicant maintains that the specification provides lists of examples of each domain, and exemplifies the preparation of proteins containing the domains. However, although the specification describes polypeptides consisting of an anchoring domain and a therapeutic domain, wherein the anchoring domain is selected from the sequence of SEQ ID NO: 2, 3, 4, 5, or 7 and wherein the therapeutic domain is selected from SEQ ID NO: 8 or 9. This group of sequences is not representative of the claimed genus for preventing or treating pathogenic infection. Applicant asserts that the metes and bounds of the invention claimed is clear and is commensurate with the generic concept of a new modality for preventing or treating pathogenic infection. However, no precise common definition for the described polypeptides, sufficient to distinguish the group from other chemical species, is provided in the description. A precise common definition for the combination of any anchoring activity and any therapeutic activity, as defined in the claim, to prevent infection of a eukaryotic cell by a pathogen is not substantially supported. Applicant is reminded that it is the claims that define the metes and bounds of the alleged invention, and not the description. The prosecution of an application allows for the clarification of any perceived ambiguity of any claimed subject matter. Also, Applicant is reminded that a person skilled in the art should be able to read a claim and make

sense of it without first having to read the description (Lishman v Erom Roche Inc [1996] 68 CPR (3d) 72 at 77-78 (FCTD) affirmed [1998] 71 CPR (3d) 146 (FCA)). Furthermore, according to section 11.02 of MOPOP "[e]ven though claims are construed with reference to the description, reference to the description is only permitted to assist the understanding of the terms used within the claims if these terms have a unique meaning". Therefore, the objection is maintained.

In view of this, it follows that this application does not comply with subsection 27(3) of the Patent Act . The specification does not correctly and fully describe the myriad of possible combinations of any anchoring activity and any therapeutic activity to prevent infection of a eukaryotic cell by a pathogen.

Claims 7, 10, 23 - 27 and 29 - 32 are indefinite and do not comply with subsection 27(4) of the *Patent Act*. The inclusion of "essentially" causes ambiguity. This expression implies unspecified changes.

Claims 10, 11, 20, 24 - 26, 54 and 55 do not comply with subsection 87(2) of the *Patent Rules*. Dependent claims must refer to preceding claims.

Claims 10, 21, 23 - 27, and 29 - 32 are indefinite and do not comply with subsection 27(4) of the *Patent Act*. The "activity" (10, 23 - 27, and 29 - 32) is not clearly and explicitly defined. It is not clear what type of activity or what level of activity is referred to. Further, the phrase "the active portion thereof" (claim 21) is unclear because the region on the enzyme is not defined in clear and explicit terms.

Claim 11 is indefinite and does not comply with subsection 27(4) of the Patent Act. The claimed composition has no antecedent and possibly should be directed to a polypeptide.

Claim 31 is broader in scope than the teaching of the description. To comply with section 84 of the *Patent Rules* the claim must specify NEU2 (SEQ ID NO: 8) or NEU4 (SEQ ID NO 9). Applicant does not have substantial factual or literal support for using the sialidase activity of NEU1 or NEU3 in the therapeutic domain.

Claim 33 is indefinite and does not comply with subsection 27(4) of the *Patent Act*. The phrase "at least anchoring domain" causes ambiguity.

Claims 49 and 50 are indefinite and do not comply with subsection 27(4) of the *Patent Act*. The term "said compound" (claims 49 and 50, line 1) has no antecedent.

Claims 49 - 51, 57 and 58 are ambiguous and do not comply with subsection 27(4) of the *Patent Act*. As currently formulated, theses use claims could be interpreted to encompass a method of medical treatment because they include a method step. Claims which are directed to a use rather than a method of medical treatment may be acceptable as long as no method steps are included in the claims. The phrase "wherein said polypeptide is used" defines an active method step. Therefore, this claim must be amended to delete or avoid encompassing all active steps (see Section 11.10.02 of the Manual of Patent Office Practice).

Claims 49 to 58 are directed to a method of medical treatment that does not produce an essentially economic result in relation to trade, commerce, or industry, and is therefore outside the definition of invention in section 2 of the *Patent Act*. (See Tennessee Eastman v. Commissioner of Patents (1974) S.C.R. 111, or (1972) 8 C.P.R. (2d) 202, confirmed by Imperial Chemical Industries v. Commissioner of Patents (1986) 3 F.C. 40, or (1986) 9 C.P.R. (3d) 289). 12

Claims 53 - 56 are indefinite and do not comply with subsection 27(4) of the *Patent Act*. The inclusion of "is functionally identical" causes ambiguity. The precise type of function is not clearly and explicitly defined. 13

In view of the foregoing defects, the applicant is requisitioned, under subsection 30(2) of the *Patent Rules*, to amend the application in order to comply with the *Patent Act* and the *Patent Rules* or to provide arguments as to why the application does comply.

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